OCT - 4 2011

SOVEREIGN™ Spinal System
510(k) Summary
Date Prepared: September 28, 2011

I. **Company:** Medtronic Sofamor Danek, Inc.
1800 Pyramid Place
Memphis, Tennessee 38132

Contact: Sowmya Shetty
Regulatory Affairs Specialist
Telephone: (901) 396-3133
Fax: (901) 346-9738

II. **Product Name:** SOVEREIGN™ Spinal System

Common Name: Intervertebral Fusion Device

Classification: 21 CFR 888.3080

Product Code: OVD

III. **Description:** The SOVEREIGN™ Spinal System is an intervertebral body fusion device with internal screw fixation. The screws protrude through the interbody portion of the device and stabilize the vertebral body while preventing expulsion of the implant. The implant is lens-shaped with three holes for placement of titanium screws. The SOVEREIGN™ Spinal System contains both a fixed and a variable angle screw option. The fixed angle screw option provides an interference fit with the PEEK interbody implant. The variable angle screw option provides a slight clearance between the PEEK interbody implant and the screw which allows for a small amount of variable screw angulation. This system is intended to be radiolucent and the interior space of the product is to be used with autogenous bone graft. The accompanying cover plate is designed to resist screw backout and must be used when the variable angle screws are implanted.

The SOVEREIGN™ Spinal System interbody device is manufactured from PEEK Optima® (polyetheretherketone) and contains tantalum radiopaque markers. The screws used with this device are manufactured from titanium alloy.

IV. **Indications for Use:** The SOVEREIGN™ Spinal System is indicated for use with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. These implants may be implanted via a laparoscopic or an open anterior approach.

The SOVEREIGN™ Interbody System may be used as a stand-alone device or in conjunction with supplemental fixation.

When used as a stand-alone device, the SOVEREIGN™ interbody device is intended to be used with the three titanium alloy fixed or variable angle screws. The accompanying cover plate MUST be used anytime the device is used with any number of variable angle screws. If the physician chooses to use less than three or none of the provided screws, then additional supplemental fixation for use in the lumbar spine must be used to augment stability.

V. Summary of the Technological Characteristics:

The purpose of this 510(k) is to include modified screws to the SOVEREIGN™ Spinal System. The new subject screw contains a larger major diameter near the head of the screw which will allow some interference between the screw and implant.

This system is cleared for indications from levels L2 to S1. The SOVEREIGN™ Spinal System is an intervertebral body fusion device with internal screw fixation. The SOVEREIGN™ Spinal System is manufactured from PEEK Optima® (polyetheretherketone) and contains tantalum radiopaque markers. The screws used with this device are manufactured from titanium alloy.

The subject and the predicate SOVEREIGN™ Spinal System are substantially equivalent in terms of design, material, indications for use, intended use and fundamental technology.

VI. Identification of Legally Marketed Devices:

The design features, materials, and indications for use of the subject SOVEREIGN™ Spinal System fixed angle screws are substantially equivalent to the previously cleared predicate SOVEREIGN™ Spinal System (K091813 – S.E. 11/17/2009).

VII. Discussion of the Non-clinical Testing:

Medtronic believes that documentation provided demonstrates that the subject SOVEREIGN™ Spinal System devices do not introduce new issues of safety or effectiveness. The following testing was performed on the subject device:

1. Static Screw Push-out Testing
2. Static Compression Testing in accordance with ASTM Standard F2077-03 "Test Methods for Intervertebral Body Fusion Devices"
3. Compression Fatigue Testing in accordance with ASTM Standard F2077-03 "Test Methods for Intervertebral Body Fusion Devices"
4. Static Compression-Shear Testing in accordance with ASTM Standard F2267-04 "Standard Test Method for Measuring Load Induced Subsidence of an Intervertebral Body Fusion Device under Static Axial Compression"
5. Compression-Shear Fatigue in accordance with ASTM Standard F2267-04 "Standard Test Method for Measuring Load Induced Subsidence of an Intervertebral Body Fusion Device under Static Axial Compression"

6. Static Subsidence Testing in accordance with ASTM Standard F2267-04 "Standard Test Method for Measuring Load Induced Subsidence of an Intervertebral Body Fusion Device under Static Axial Compression"
7. Analysis of Particulate from Fatigue Testing in accordance with ASTM Standard F1877-05 "Standard Practice for Characterization of Particles"

VIII. Conclusion:

Based on the non-clinical testing conducted in accordance with ASTM F2077 and ASTM F2267 and additional supporting documentation provided in this premarket notification, the subject device demonstrated substantial equivalence to the predicate SOVEREIGN™ Spinal System (K091813 – S.E. 11/17/2009) in terms of design, intended use, indications for use and fundamental technology.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - W066-G609
Silver Spring, MD 20993-0002

Medtronic Sofamor Danek, Inc.
Spinal and Biologics
% Ms. Sowmya Shetty
1800 Pyramid Place
Memphis, Tennessee 38122

OCT - 4 2011

Re: K110063
Trade/Device Name: Sovereign™ Spinal System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: OVD
Dated: September 06, 2011
Received: September 07, 2011

Dear Ms. Shetty:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin M. Keith

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K110063

Device Name: SOVEREIGN™ Spinal System

Indications for Use:

The SOVEREIGN™ Spinal System is indicated for use with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. These implants may be implanted via a laparoscopic or an open anterior approach.

The SOVEREIGN™ interbody system may be used as a stand-alone device or in conjunction with supplemental fixation.

When used as a stand-alone device, the SOVEREIGN™ interbody device is intended to be used with the three titanium alloy fixed or variable angle screws. The accompanying cover plate MUST be used anytime the device is used with any number of variable angle screws. If the physician chooses to use less than three or none of the provided screws, then additional supplemental fixation for use in the lumbar spine must be used to augment stability.

Prescription Use ____X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K110063